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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,581	02/22/2001	Paolo Mascagni	205,042	9301
7590 04/07/2004				
Abelman Frayne & Schwab 150 East 42nd Street New York, NY 10017-5612				
EXAMINER MAIER, LEIGH C				
ART UNIT		PAPER NUMBER		
1623				
DATE MAILED: 04/07/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/763,581	MASCAGNI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leigh C. Maier	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 28, 2004 has been entered.

Claims 29-42 have been amended. Claims 29-44 are pending. Any objection or rejection not expressly repeated has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

Claims 29 and 32-44 are rejected under 35 U.S.C. 102(b) as being anticipated by RONSEN et al (WO 99/16440).

RONSEN teaches the formation of a paroxetine/HPCD complex as set forth in Office actions mailed February 12, 2003 and July 24, 2003. The claims have been amended to more specifically define the nature of the complexation, reciting an "inclusion complex." It is Applicant's position that the present invention can be distinguished from the reference product because the DSC thermogram of the reference compound shows two peaks whereas these peaks are absent in the present product. This is not found to be persuasive because an inclusion product, as one component of a mixture, would not necessarily be detected by this method. For example, if one were to prepare a mixture of the present product and the RONSEN product,

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followed by DSC, the resulting peak would not negate the presence of the inclusion product. The claim requires only the existence of some inclusion product.

Because the product is prepared by a method that is known in the art for preparing inclusion products, it would appear more likely than not that some inclusion product is present in the RONSEN product. Furthermore, as noted by RONSEN, amorphous paroxetine is hygroscopic, so it also appears likely that some water would be present in the product. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

### ***Claim Rejections - 35 USC § 103***

Claims 29 and 32-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over RONSEN et al (WO 99/16440) in view of BENNEKER et al (US 5,874,447).

RONSEN teaches as set forth above. The reference does not teach the preparation of the complex comprising paroxetine and the full scope of claimed salts. BENNEKER teaches as set forth in Office actions mailed February 12, 2003 and July 24, 2003.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a paroxetine complex such as that taught by RONSEN as any salt known in the art such as those taught by BENNEKER with a reasonable expectation of success.

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Claims 29-35 and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over UEKAMA et al (US 5,904,929).

UEKAMA teaches the preparation of clathrates of therapeutic agents and TV- $\beta$ -CD. See abstract; col 5, lines 22-26; col 6, lines 28-35; 7, lines 53-60; and examples 3-13. The reference does not exemplify the use of paroxetine HCl, but its use is specifically suggested.

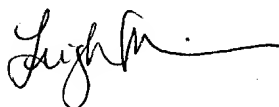
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify any of the products disclosed in the examples by the substitution of paroxetine HCl. One of ordinary skill would reasonably expect success in making this modification because it was specifically suggested by the art. The artisan would be motivated to make this substitution for the art-disclosed utility of preparing a control-release product.

*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier  
Patent Examiner  
April 2, 2004